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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,969	04/30/2007	Tohru Natsume	039371-17	8384

25570

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01/23/2009

ROBERT'S MLOTKOWSKI SAFRAN & COLE, P.C.

Intellectual Property Department

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

01/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/581,969

**Applicant(s)**

NATSUME ET AL.

**Examiner**

Maryam Monshipouri

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1 and 6, drawn to a mixture comprising SEQ ID NO:1 or 2 and proteasome and a method of use thereof for producing a therapeutic agent for treatment of disuse muscular atrophy.

**Group II**, claim(s) 2 and 10, drawn to a mixture of SEQ ID NO:1 or 2 and polyubiquitin chain and a method of use thereof for producing a therapeutic agent for treatment of disuse muscular atrophy.

**Group III**, claim 3, drawn to a therapeutic agent wherein the function of SEQ ID NO:1 or 2 is inhibited.

**Group IV**, claim 4, drawn to a therapeutic agent wherein an interaction between SEQ ID NO:1 or 2 and proteasome is inhibited.

**Group V**, claim 5, drawn to a therapeutic agent wherein an interaction between SEQ ID NO:1 or 2 and a polyubiquitin chain is inhibited.

**Group VI**, claim 7, drawn to a method of screening for therapeutic agents utilizing a mixture between SEQ ID NO:1 or 2 and proteasome.

**Group VII**, claim 8, drawn to a marker for disease diagnosis for disuse muscular atrophy utilizing SEQ ID NO:1 or 2 and a proteasome.

**Group VIII**, claim 9 drawn to method of evaluating the risk of onset of disuse muscular atrophy utilizing a mixture of SEQ ID NO:1 or 2 and protease.

**Group IX**, claim 11, drawn to a method of screening for therapeutic agents utilizing a mixture of SEQ ID NO:1 or 2 and a polyubiquitin chain.

**Group X**, claim 12, drawn to a marker for disease diagnosis for disuse muscular atrophy utilizing SEQ ID NO:1 or 2 and a polyubiquitin chain.

**Group XI**, claim 13, drawn to a method of evaluating the risk of onset of disuse muscular atrophy utilizing a mixture of SEQ ID NO:1 or 2 and a polyubiquitin chain.

In addition to inventions listed as Groups I-XI above each invention is additionally and independently directed to the following patentably distinct inventions:

- (a) SEQ ID NO:1, and
- (b) SEQ ID NO:2

When electing any of the inventions of Groups I-XI applicant is advised to simultaneously elect an invention from Groups (a)-(b) as well. **This is not a species election.**

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Groups I, II, III, IV, V, VII and X are:  
a mixture of SEQ ID NO:1 or 2 and proteasome, a mixture of SEQ ID NO:1 or 2 and a polyubiquitin chain, a therapeutic agent wherein the function of SEQ ID NO:1 or 2 is inhibited, a therapeutic agent wherein interaction of SEQ ID NO:1 or 2 and proteasome is inhibited, a therapeutic agent wherein interaction of SEQ ID NO:1 or 2 and a ubiquitin chain is inhibited, a marker of a disease wherein the interaction of SEQ ID NO:1 or 2 and proteasome is inhibited, a marker of a disease wherein the interaction of SEQ ID NO:1 or 2 and a ubiquitin chain is inhibited, respectively, which are each products of unrelated chemical structure and function.

The inventions of Group VI and VII share a special technical feature with Group I invention, namely: a method of use of a mixture of SEQ ID NO:1 or 2 and proteasome. However under PCT Rule 13.1 said inventions are not required to be rejoined because Group I already has a method of use of SEQ ID NO:1 or 2 and proteasome.

Similarly, the inventions of Group XI and XI share a special technical feature with Group II invention, namely: a method of use of a mixture of SEQ ID NO:1 or 2 and a polyubiquitin chain. However under PCT Rule 13.1 said inventions are not required to be rejoined because Group II already has a method of use of SEQ ID NO:1 or 2 and a polyubiquitin chain.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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